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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,876	08/04/2003	Ron L. Hale	00060.01R	5253

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
10/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/633,876	HALE ET AL.	
	Examiner	Art Unit	
	MINA HAGHIGHATIAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/24/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Haghighatian. Contact information are as below.

Election/Restrictions

Receipt is acknowledged of the Election of species made by applicant filed on 07/29/08. However upon further consideration, the requirement for election of species has been **withdrawn**. All claims (1-28) are herein examined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull et al (6,041,777) in view of Bartus et al (6,514,482).

Faithfull teaches methods and apparatus for closed-circuit ventilation therapy. In procedures involving liquid ventilation, this treatment and recirculation of the exhaled gases, vapors or liquids substantially reduces the amount of respiratory promoter needed to provide effective ventilation (col. 10, lines 13-26). Faithfull discloses that the nebulizer is used to provide fluorochemicals, heated above body temperature, to the ventilating gas in the form of a vapor. This may be accomplished by spraying or contacting a wetted surface or wick with the gas to form droplets. The fluorochemical liquid medium is particularly well dispersed in the lungs. As the fluorochemical vapor cools in the body it is deposited on the pulmonary surfaces (col. 16, lines 44-67).

Faithfull also discloses that the said method provides for the independent delivery of pharmaceutical agents or their use in conjunction with other vapors (col. 25, lines 15-30). Faithfull lacks on specifics of drugs.

Bartus teaches a method of pulmonary delivery of a medicament, which includes administering to the pulmonary system and in particular to the alveoli or the deep lung particles comprising an effective amount of a medicament, where the particles preferably have an aerodynamic diameter between about 1 and about 5 μm. Particles can consist of the medicament or can further include one or more additional

components. Rapid release of the medicament into blood stream and its delivery to its site of action (col. 3, lines 41-59).

Bartus discloses that medicaments which can be used in the said method include lorazepam, apomorphine, donapezil, buprenorphine hydrochloride, hydromorphone, butorphanol, nalbuphine, naltrexone, oxycodone, etc, (col. 6, lines 49-63).

In a preferred embodiment, Bartus discloses that particles are delivered from an inhalation device, preferably they are administered via a dry powder inhaler (DPI), metered dose inhaler (MDI), nebulizers or instillation techniques. Various suitable devices and methods of inhalation which can be used are known in the art (col. 7, line 24 to col. 8, line 8).

Bartus discloses that at least 50% of the mass of the particles stored in the inhaler receptacle is delivered to a subject's respiratory system in a single breath activated step. Amounts of drug or medicament present in the particles can range from 1 to about 90 weight percent (col. 8, lines 26-41).

While neither reference specifically discloses a temperature range or time period for volatilizing the active agents, it is known that the device needs to heat the substrate to its voltilizing temperature of the active agent and for the time period needed to volatilize the active agent, in order for the agent to volatilize and condense for inhalation. Thus the said limitations are necessarily present.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the method of delivering a medicament to a

patient's respiratory tract by heating the composition and having patient inhale the condensates, as taught by Faithfull et al, by adding the specific drugs and their amounts as taught by Bartus et al because of the benefits of employing such a method with various active agents for variety of treatemtents and because the method provides for minimized trauma to the lungs and a better resolution of pulmonary and systemic disorders. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Furthermore one of ordinary skill in the art would know that condensates have a high percentage of purity of the drug and less degradation products. Also noted that optimization of concentration ranges will not support patentability.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byron et al (20040016427 A1) in view of Bartus et al (6,514,482).

Byron et al disclose a method and apparatus for generating an aerosol. The aerosol is formed by supplying a material in liquid form to a tube and heating the tube such that the material volatizes and expands out of an open end of the tube. The volatized material combines with ambient air such that volatized material condenses to form the aerosol (see abstract and [0012]). The organic material is heated to a temperature of less than 400 °C. The volatilized material mixes with ambient air outside

of the flow passage and condenses to form particles, thereby forming an aerosol (see [0034]). The aerosols intended for inhalation typically have a mass median particle diameter of less than 2 microns (see [0074]).

Byron et al disclose that the apparatus may be fairly large or may be miniaturized to be hand held (see [0086]). Byron lacks disclosure on specific drugs and their amounts.

Bartus, discussed above, discloses respiratory delivery of various systemic active agents in their purest form.

While neither reference specifically a time period for volatilizing the active agents, it is known that the device needs to heat the substrate to its voltilizing temperature of the active agent and for the time period needed to volatilize the active agent, in order for the agent to volatilize and for the condensate for inhalation. Thus the said limitation is necessarily present.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the aerosol device article of Byron et al for delivering the aerosolized compositions of Bartus to a subject's respiratory tract because it would be desirable to provide an aerosol delivery article which is capable of producing condensate aerosol particles of relatively small size without the necessity of subjecting the material to be aerosolized to exposure to a significant degree of heat or

high temperatures. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Also noted that optimization of concentration ranges will not support patentability.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1-28** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 7,090,830 in view of Byron et al (20040016427). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims would have been obvious over the reference claims. Here claims **1-28** are drawn to an article for use in an aerosol device for producing an aerosol comprising a substrate and a drug. The reference claims are drawn to a composition for delivery of a drug comprising a condensation aerosol wherein the drug is a heat stable drug. Byron et al teaches the device for heating and condensing active agents for inhalation. It would have been obvious to one of ordinary skill in the art to have implemented the article of Byron et al in the process of making the composition. In other words, the article for preparing the compositions of the instant claims would have been obvious over the compositions of U.S. Patent No. 7,090,830 in view of Byron et al.

Claims **1-28** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of co-pending Application No.10/633,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims would have been obvious over the reference claims. Here claims **1-28** are drawn to an article for use in an aerosol device for producing an aerosol comprising a substrate and a drug. The reference claims are drawn to a device for producing a condensation aerosol comprising a chamber, a substrate and a drug composition. It would have been obvious to one of ordinary skill in

the art to have implemented the article of the instant claims in the device of the reference claims for making the condensation aerosol composition. In other words, the article for preparing the compositions of the instant claims would have been obvious over the device of the reference claims. The drugs in both sets of claims are the same.

Claims **1-28** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of co-pending Applications No.10/437,643; 10/057,197 and 10/057,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims would have been obvious over the reference claims. Here claims **1-28** are drawn to an article for use in an aerosol device for producing an aerosol comprising a substrate and a drug. Claims of '643 are drawn to a condensation aerosol for delivery of a drug amine, the claims of '197 are drawn to a method of generating an aerosol and claims of '198 are drawn to a method of delivering an active compound in a form of a condensate. It would have been obvious to one of ordinary skill in the art to have implemented the article of the instant claims in the methods and compositions of the reference claims. In other words, the article for preparing the compositions of the instant claims would have been obvious over the device of the reference claims.

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616